BILL FRIST, M.D.
TENNESSEE

United States Senate

OFFICE OF THE MAJORITY LEADER
WASHINGTON, DC 20510-7010

July 1, 2005

The Honorable David M. Walker
Comptroller General of the United States
Government Accountability Office
441 G Street, NW, Room 7100
Washington, DC 20401

Dear Mr. Walker,

Just last week a new study reported that total health care spending per privately insured American increased by 8.2 percent in 2004. While the 2004 rate of growth is relatively unchanged from 2003, it marks yet another year in which health care spending outpaced overall economic growth and the growth in wages. Most disconcerting, the study finds that following a deceleration in cost growth trends these trends have stabilized at a relatively high rate of growth.

As policymakers and patients consider approaches to make health care more affordable and accessible and to strengthen the safety of prescription drugs, one continuing area of focus is direct-to-consumer (DTC) advertising. In 2002, the Government Accountability Office (GAO) issued a report regarding the direct-to-consumer (DTC) advertising of prescription drugs, noting that pharmaceutical manufacturers have more rapidly increased spending on DTC advertising than spending on research and development. For example, between 1997 and 2001, DTC advertising spending increased by 145 percent, whereas research and development spending increased by 59 percent. And, spending on television advertising rose to 64 percent of all DTC spending in 2001, as opposed to 25 percent of all DTC spending in 1997.

The GAO concluded that "DTC advertising appears to increase prescription drug spending and utilization. Drugs that are promoted directly to consumers often are among the best-selling drugs, and sales for DTC-advertised drugs have increased faster than sales for drugs that are not heavily advertised to consumers. Most of the spending increase for heavily advertised drugs is the result of increased utilization, not price increases." In the three years since the GAO's report, mounting drug safety concerns, particularly regarding newly-approved, heavily advertised pharmaceuticals, have renewed discussion regarding the impact, appropriateness, and effectiveness of DTC advertising. As a result, I respectfully request that you conduct an independent evaluation, examining the Food and Drug Administration's (FDA) regulation and oversight of DTC advertising as well as exploring DTC advertising's potential impact on utilization, health care spending, and patient education and awareness.

Among the areas you explore, I hope you will consider the following questions:

- In 2004, how much did pharmaceutical manufacturers spend on promotional activities, specifically DTC advertising? Of this, how much was spent on televised advertisements?

- Between 1997 and 2004, how has spending on DTC advertising, specifically televised advertisements, changed over time in relation to spending on research and development? Additionally, is there a trend in the types of pharmaceuticals advertised directly to patients?

- How many prescriptions were dispensed in 2004? Is there any correlation between the volume of prescriptions dispensed and spending on DTC advertising? Are there additional contributing factors to increased utilization? And, if so, what are these factors?

- For both broadcast and print advertisements and promotional materials of heavily advertised products, how are risks and benefits discussed, including the visual images used? On average, how much time do ads give patients to absorb risk information? What available evidence is there that DTC ads achieve the FDA's "fair balance" requirement and include critical risk and adverse event statements?

- Often, broadcast advertisements direct patients to secondary sources of product information in order to fulfill the FDA's "adequate provision" requirement. How closely does the FDA monitor such secondary sources? Do you find these secondary sources to be easily accessible, comprehensible, and balanced?

- Does DTC advertising impact the physician-patient relationship? And, if so, how?

- Are there any studies which have examined the types of discussions held with a physician after a patient sees a DTC ad, the actions as a result of the discussion, and the effect, if any, on health outcomes?

- What are the FDA's current financial and staff resources for reviewing pharmaceutical promotional materials? Has the quantity of available resources changed since the GAO's 2002 report? And, if so, how?

- In 2004, how many promotional materials did the Division of Drug Marketing, Advertising, and Communications (DDMAC) receive for prior review and comment? Was the DDMAC able to thoroughly review all voluntarily submitted materials prior to being publicly aired? In your view, are additional measures needed? And, if so, what measures would you recommend?

- It is my understanding that pharmaceutical manufacturers often submit a series of promotional proposals, some that are aired and others which are not aired. How does the DDMAC track aired and printed promotional materials and ensure adherence to advertising guidelines, specifically those materials which are not submitted for prior review?

- In November 2001, the Department of Health and Human Services (HHS) issued a directive, requiring that all untitled and warning letters originating within the FDA must be reviewed and cleared by the Agency's Office of the Chief Counsel. The GAO's 2002 report expressed concern that it "sharply reduced FDA's effectiveness in issuing untitled and warning letters in a timely matter." Does the GAO still find this to be the case? Has the agency acted to expedite the review of DTC regulatory letters?

Thank you for your consideration of this request. If you have any questions, please do not hesitate to contact Dean Rosen of my staff at (202) 224-5589. I look forward to your prompt response.

Sincerely,

William H. Frist

William H. Frist, M.D.
Majority Leader
United States Senate